

K032945

MAY 25 2004

stryker  
INSTRUMENTS

4100 East Milham Avenue  
Kalamazoo, MI 49001  
Phone (269) 323-7700  
(800) 253 3210

## 510(k) Summary

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**Trade Name:** Stryker Spineplex™ Radiopaque Bone Cement

**Common Name:** PMMA bone cement

**Classification:** Bone Cement, 888.3027

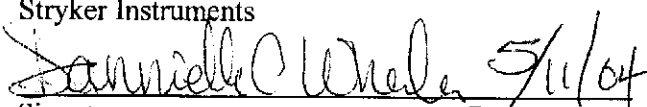
**Equivalent to:** Stryker Simplex® P

**Device Description:** Stryker Spineplex™ Radiopaque Bone Cement is a PMMA bone cement made of the same chemical components as Stryker Simplex® P.

**Intended Use:** Spineplex™ Radiopaque Bone cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

**Technological Comparison:** Stryker Spineplex™ Radiopaque Bone Cement is made of the exact components a Simplex™ P. The ratio of the ingredients has been modified to increase the working time and enhance visualization of the cement to meet customer needs in the fixation of vertebral compression fractures.

**Submitted by:** Dannielle C. Wheeler  
Sr. Regulatory Affairs Representative  
Stryker Instruments

  
Signature Date 5/11/04

**Date Submitted:** Sept. 19, 2003



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 25 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Dannielle Wheeler  
Senior Regulatory Affairs Representative  
Stryker Corporation  
Instrument Division  
4100 East Milham Avenue  
Kalamazoo, Michigan 49001

Re: K032945

Trade/Device Name: Spineplex™ Radiopaque Bone Cement  
Regulation Number: 21 CFR 888.3027  
Regulation Name: PMMA Bone Cement  
Regulatory Class: II  
Product Codes: LOD, NDN  
Dated: February 27, 2004  
Received: March 1, 2004

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

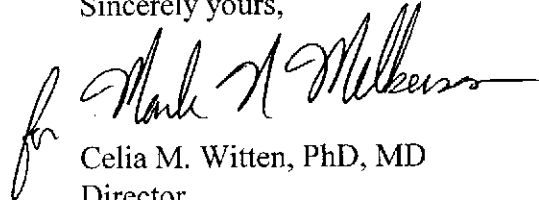
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Dannielle Wheeler

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, PhD, MD  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K032945

Device Name: Spineplex™ Radiopaque Bone Cement

Indications for Use:

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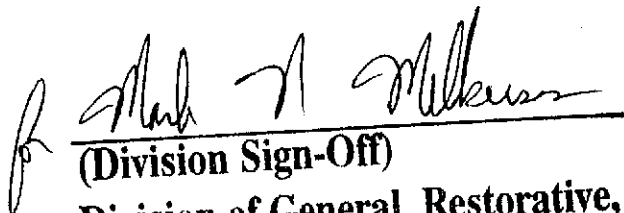
Prescription Use ☒   
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_   
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRII, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K032945

Page 1 of 1